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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/051,034	03/31/1998	IAN FARQUHAR CAMPBELL MCKENZIE	3164.98USWO	7533

23552 7590 12/24/2002

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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 12/24/2002

3/4

Please find below and/or attached an Office communication concerning this application or proceeding.

File

**Advisory Action**Application No.  
**09/051,034**Applicant(s)  
**McKenzie et al.**Examiner  
**Joseph Weitach**Art Unit  
**1632**

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

THE REPLY FILED Dec 17, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Dec 17, 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attached.

3. ☐ Applicant's reply has overcome the following rejection(s):
- \_\_\_\_\_

4. ☒ Newly proposed or amended claim(s) 37, 39, 43, 45, and 47 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attached.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: 31

Claim(s) rejected: 1-10, 12-14, 17-24, 26-30, and 32-35

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

10. ☒ Other: See attached.

*msk*  
**RAM R. SHUKLA, PH.D.**  
**PATENT EXAMINER**

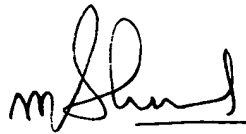
Art Unit: 1632

Section 2(a): Claim 36 recites the limitation for localization "to the Golgi of a cell" which has not been previously searched or specifically considered, and raises issues of written description under 35 U.S.C. 112, first paragraph and consideration of the art for modified fucosyltransferases as enzymes which meet the limitations of the claims. Claim 41 does not narrow the limitations set forth in claim 37 and raises new issues under 35 U.S.C. 112, second paragraph. While methods of gene therapy have been generally considered, claims 52 and 53 recite a new limitation that the method is practiced *ex vivo* and claims 54 and 55 recite that the cells are isolated from a species of porcine, which were not specifically considered, and raises new issues under 35 U.S.C. 112, first paragraph.

Section 5: Applicants' arguments are primarily directed to the newly proposed claims which have not been entered. To the extent arguments apply to the pending claims, Examiner agrees that product claims 37, 39, 43, 45 and 47 are directed to embodiments which have been previously considered and free of the art of record, and would be allowed if presented in a separate amendment (see Section 4 of Advisory action). With respect to method claims directed to reducing the amount of gal-alpha (1,3)-gal on the surface of a cell, Examiner would agree to the extent that the claims encompass transducing isolated cells *in vitro*, the methods are enabled, however methods for transducing cells *in vivo* or whole tissues *in vivo* or *ex vivo* are subject to the limitations of gene therapy recognized in the art as set forth in the basis of the rejections of record.

Art Unit: 1632

Section 10: Upon review of the disclosure, it was found that the specification contained amino acid sequences which were not identified by SEQ ID NOs nor listed in a sequence listing. See for example page 20, lines 5 and 35. Therefore, the specification is objected to because the sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

  
**RAM R. SHUKLA, PH.D**  
**PATENT EXAMINER**